DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-03-03

October 2, 2002

Jeffrey P. Hazell, President
Bar Harbor Lobster Company
2000 Premier Row
Orlando, Florida 32809

Dear Mr. Hazel:

We inspected your seafood processing and cold storage facility, located at the above address, on June 21, 2002 and found that you continue to have serious deviations from the Seafood HACCP Regulations (21 CFR Part 123). These deviations cause your refrigerated canned pasteurized crabmeat products and your fresh refrigerated scombrotoxin forming fish products such as mahi, tuna and wahoo to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders your seafood products adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly your refrigerated canned pasteurized crabmeat products and your fresh refrigerated scombrotoxin forming fish products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 through links in FDA's home page at http://www.fda.gov.

The deviations are as follows:

You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for Fish and Fishery Products does not list the food safety hazard of scombrotoxin (histamine) formation. Your firm currently receives and processes fresh tuna, wahoo, and mahi mahi. You must provide controls to assure that the histamine has been adequately controlled during transport to your firm and during storage. Refer to Chapter 7 of the FDA Fish & Fisheries Products Hazards and Controls Guidance.

Third Edition. June 2001 for information on how to control the food safety hazard of histamine in your fish and fishery products.

You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Fish and Fishery Products lists a monitoring procedure at the Receiving critical control point that is not adequate to control the hazard of *Clostridium botulinum* (pathogen growth and toxin formation) in the refrigerated canned crabmeat you receive. FDA has determined that intermittent monitoring of ambient or internal temperatures does not supply the necessary safety assurance that ready-to-eat or refrigerated vacuum-packed products have been consistently shipped and stored under safe conditions. FDA recommends that temperatures be monitored by a continuous monitoring device instead. Another option is to monitor the adequacy of the cooling media upon receipt and then twice a day during storage.

You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of "checking unit recording device" at the Storage critical control point to control *Clostridium botulinum* (pathogen growth and toxin formation) as listed in your HACCP plan for Fish and Fishery Products (including refrigerated pasteurized crabmeat). Your employee checks and records the temperature displayed on the LCD for your cooler. You did not appear to have a continuous recording device for the cooler at the time of inspection. Please be aware that FDA recommends monitoring procedures for refrigerated storage of ready-to-eat and vacuum-packed products that are similar to those recommended during shipping, i.e., some method of continuous monitoring of cooling/storage conditions.

Since you chose to include corrective actions in your HACCP plan for Fish and Fishery Products, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans for refrigerated canned crabmeat at the Receiving and Cold Storage critical control point to control *Clostridium botulinum* (pathogen growth and toxin formation) are not appropriate.

> You list that you will reject product that exceeds an internal temperature of 50 degrees F at your Receiving critical control point. Your critical limit is 41 degrees F. Corrective action must be taken when the critical limit is exceeded.
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> In addition, you list that you will reject product that has been exposed to temperatures higher than 41 degrees F for four hours. You do not have a method for determining how long the product has been exposed to elevated temperatures.
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> You have listed that you will move product from any cooler if

the unit temperature rises above 45 degrees F. Your critical limit is 41 degrees F. You must take corrective action when your critical limit is exceeded. Your listed corrective action does not address how your firm will correct cooler conditions.

In addition, our investigator documented that the temperature sensor in the fish cooler, used to store fresh fish and fishery products, was not being calibrated and your HACCP plans were not signed and dated by a responsible individual to signify that the plans had been accepted for implementation by your firm.

During a discussion of inspectional observations at the conclusion of the inspection, your general manager, Alan C. Brown, promised to relay the concerns to you and work toward prompt correction. We have received no documentation of any corrective action taken by your firm.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice (GMP) Regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your revised HACCP plan, cooler temperature monitoring records, written specifications for imported products, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District